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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,372	06/04/2001	Roland Henri	JAB-1430	3181

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,372

Applicant(s)

HENRI ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment filed December 19, 2005 has been received and entered. Claims 1-46 have been canceled and new claims 47-59 have been added. Consequently, claims 47-59 are pending in the instant application.

Claim Rejections - 35 USC § 101

1. The rejection of claims 36 and 42 under 35 USC 101 as the claimed invention is directed to non-statutory subject matter is withdrawn in view of the cancellation of said claims.

Claim Rejections - 35 USC § 112

2. The rejection of claims 31-46 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained as applied to newly added claims 47-59.

Applicants are asserting that the nine sequences are described in the specification, at pages 39-40 as well as the sequence listing.

Applicants arguments have been fully considered but are not found to be persuasive.

First, this is not a new matter rejection. The Examiner has not taken the position that SEQ ID NO: 1-9 are not disclosed by the specification. However, this rejection is applied under the written description guidelines Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. In a nutshell, Applicants disclosed sequences (e.g., SEQ ID NO:

1) is only a fragment of a full length gene. Without disclosure of a reading frame, the start codon and the stop codon, Applicants have only described the precisely identified fragment.

Accordingly, Applicants claims are only able to satisfy the written description guidelines for this precise fragment (i.e., consisting of SEQ ID NO: 1). Applicants claims recite a nucleic acid molecule encoding a polypeptide which is critical for survival and growth of *C. albicans*. This allows for additional upstream and downstream nucleotides, beyond that which Applicants have described. It is precisely these regions, which will have a profound impact on the activity of the encoded polypeptide, which are not adequately described by Applicants specification, and accordingly do not meet the written description guidelines.

Claims 47-59 recite nucleic acid molecules encoding polypeptides, which nucleic acid is selected from the group consisting of SEQ ID NO: 1-9.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a “non-full length open reading frame of SEQ ID NO: 1-9” alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. Specifically, SEQ ID NO: 1 is only a fragment of a full length open reading frame as the traditional starting codon for methionine is absent. Absent such a disclosure,

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Applicants specification is only adequately supported for “consisting of” language, as additional upstream or downstream nucleotides would have a profound impact on the activity of the encoded protein, and Applicants specification is silent as to the identity of these regions.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claim 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the cancellation of said claim.

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4. The rejection of claims 35 and 38 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "an antisense molecule comprising an isolated nucleic acid molecule encoding a polypeptide..." is withdrawn in view of the cancellation of said claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 45-46 under 35 U.S.C. 102(b) as being anticipated by Butler et al is maintained as applied to newly added claims 51 and 54.

The claims are directed to an antisense molecule comprising a nucleic acid capable of hybridizing to an isolated nucleic acid molecule encoding a polypeptide which is critical for survival and growth of *C. ablicans* wherein the nucleic acid molecule is selected from the group consisting of SEQ ID NO: 1-9.

Butler et al (US Patent Number 5,576,428) disclose of nucleotides 3892-3911 of SEQ ID NO: 3 which comprises 20 consecutive nucleotides in common with nucleotides 317-336 of SEQ ID NO: 4 of the instant invention.

It is noted that Applicants do not define the physical and chemical conditions under which the hybridization takes place. Accordingly, given that both the molecule disclosed by Butler et al and the instantly claimed nucleic acid molecule share 20 consecutive nucleotides, it is deemed to be inherently "capable" of hybridizing under certain conditions. Accordingly, each and every limitation is addressed by the teaching of Butler et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
February 23, 2006